

# Notice of Allowability

Application No.

10/800,361

Examiner

Louise Humphrey, Ph.D.

Applicant(s)

GAGE ET AL.

Art Unit

1648

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/6/06.
2. ☒ The allowed claim(s) is/are 1-8, 10, 15 and 20.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Art Unit: 1648

In the response filed on 6 March 2006, Applicants stated: "A Supplemental Reissue Declaration will be provided upon receipt of the Examiner's comments on these amendments." As indicated on page 2, line 14, in the prior Office Action mailed on 5 January 2006, the Examiner withdrew the rejection to the Oath and Declaration in view of the Supplemental Oath and Declaration filed on 14 November 2005. Therefore, no further supplemental Oath and Declaration is required for this application.

Claims 1-8, 10, 15, and 20 are pending and allowable.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kraig Anderson (Reg. No. 54,961) on 29 March 2006.

Please cancel claims 9, 11-14, 16-19, and 21-23.

Please amend claims 1, 10, 15 and 20 as per the attached Examiner's Amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louise Humphrey, Ph.D.  
Assistant Patent Examiner  
29 March 2006



JEFFREY STUCKER  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

1. A screening method for determining ion channel modulating activity of a test substance having potential for such modulating activity, which comprises the steps of:
  - (i) contacting a host cell with the test substance, said host cell expressing a peptide, polypeptide or protein in the plasma membrane [of a host cell], said peptide, polypeptide or protein having ion channel activity when expressed as a heterologous protein in the plasma membrane of the host cell; and
  - [(ii) contacting said host cell with the test substance; and]
  - [(iii)] (ii) determining changes to the ion channel activity of said heterologous protein induced by the test substance, wherein the changes to the ion channel activity of the heterologous protein induced by the test substance are determined by detecting the effect of the test substance on changes in net movement across the plasma membrane of the host cell of small cellular metabolite molecules which do not directly permeate the ion channel formed by said heterologous protein.
10. [The method of claim 9] A screening method for determining ion channel modulating activity of a test substance having potential for such modulating activity, which comprises the steps of:
  - (i) contacting a host cell with the test substance, said host cell expressing a peptide, polypeptide or protein in the plasma membrane, said peptide,

polypeptide or protein having ion channel activity when expressed as a heterologous protein in the plasma membrane of the host cell; and  
(ii) determining changes to the ion channel activity of said heterologous protein induced by the test substance, wherein the changes to the ion channel activity of the heterologous protein induced by the test substance are determined by detecting the effect of the test substance on changes in permeability of the plasma membrane of the host cell to small cellular metabolite molecules, wherein said heterologous protein having ion channel activity is the HIV-1 Vpu integral membrane protein,

wherein the effect of the test substance on changes in the permeability of the plasma membrane to proline or adenine molecules is detected.

15. [The method of claim 14] A screening method for determining ion channel modulating activity of a test substance having potential for such modulating activity, which comprises the steps of:  
(i) contacting a host cell with the test substance, said host cell expressing HIV-1 Vpu integral membrane protein in the plasma membrane, said protein having ion channel activity when expressed as a heterologous protein in the plasma membrane of the host cell; and  
(ii) determining changes to the ion channel activity of said heterologous protein induced by the test substance, wherein the changes to the ion channel activity of the heterologous protein induced by the test substance are determined by

detecting the effect of the test substance on changes in net movement across the plasma membrane of the host cell of small cellular metabolite molecules,  
wherein the effect of the test substance on changes in the movement of proline or adenine molecules is detected.

20. [The method of claim 19] A screening method for determining ion channel modulating activity of a test substance having potential for such modulating activity,  
which comprises the steps of:

- (i) contacting a host cell with the test substance, said host cell expressing HIV-1 Vpu integral membrane protein in the plasma membrane, said protein having ion channel activity when expressed as a heterologous protein in the plasma membrane of the host cell; and
- (ii) determining changes to the ion channel activity of said heterologous protein induced by the test substance,

wherein the effect of the test substance on changes in the permeability of the plasma membrane to proline or adenine molecules is detected.